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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,596	03/18/2004	Michael Lange	905.020US2	9548
21186	7590	09/07/2005	EXAMINER	
SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402-0938			CHANG, CHING	
		ART UNIT		PAPER NUMBER
		3748		

DATE MAILED: 09/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/804,596	LANGE ET AL.
	Examiner Ching Chang	Art Unit 3748

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 25 July 2005.
- 2a) This action is **FINAL**.                                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 17-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 17-40 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____.
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
	6) <input type="checkbox"/> Other: _____.

## DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on July 25, 2005 has been entered. Claims 1-16 are cancelled, and new claims 23-40 are added as requested.

### ***Claim Objections***

1. Claims 33-34 are objected to because of the following informalities:
  - " claim 25 " in claim 33 should be -- claim 26 --.
  - " claim 31 " in claim 34 should be -- claim 32 --.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
3. ***Claims 17-25, 28, 30-31, and 38-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.***

More specifically, both " the side port " in claim 17 and " the side port assembly " in claims 17-20 lack an antecedent basis, and thus render the claimed subject matter indefinite.

Furthermore, " the valve " in claim 28 lacks an antecedent basis, and thus renders the claimed subject matter indefinite.

Furthermore, " the side port coupling member " in both claims 30 and 38 lacks an antecedent basis, and thus renders the claimed subject matter indefinite.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. ***Claims 17-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Heck (US Patent 6,083,207).***

Heck discloses an introducing apparatus (See Fig.1) comprising: an elongate tubular sheath (20) having an external diameter, the sheath having a bore including an internal diameter sized to receive a dilator (300) there through, the sheath comprising a separable sheath; the sheath extending from a distal end to a proximal end; the sheath including at least one tab (204, 212) extending away from a longitudinal axis of the sheath; and a releasable side port assembly (16, 122, 124) coupled with the sheath with a coupling (18), and the releasable side port assembly includes one or more features (100) allowing for the releasable side port assembly to be released from the sheath

without damage or separation of the sheath or a side port (120); wherein the releasable side port assembly is coupled with the sheath with a snap-fit connection (102).

6. ***Claim 26 is rejected under 35 U.S.C. 102(e) as being anticipated by Heck (US Patent 6,083,207).***

Heck discloses an introducer apparatus (See Fig. 1) comprising: a sheath (20) including a sheath coupling member (204, 212), the sheath extending from a proximal portion to a distal portion; a side port assembly (16, 122, 124) including a side port coupling member (18), the side port coupling member releasably coupled with the sheath coupling member; and the side port assembly having a coupled position and an uncoupled position.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. ***Claims 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone et al. (US Patent 5,300,046) in view of West et al. (US Patent 6,322,541).***

Scarfone discloses a method comprising: providing an introducer (102) including a sheath (106, 110), a side port (124), and a side port assembly (126, 128, 130, 132)

coupled with the sheath, and fluids permitting passage (through 126).

Scarfone discloses the invention as recited above, however, fails to disclose the side port assembly being releasably coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the vascular introducer sheath and hemostasis valve art, to utilize a snap-fit connection or a threaded connection between a hub (22) and an end cap (24) of a hemostasis valve assembly, with an additional seal valve member (26) inbetween.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the snap-fit or threaded coupling or uncoupling and an additional sealing valve as taught by West, to couple or uncouple between the side port of the sheath and the side port assembly in the Scarfone method, since the use thereof would provide a more flexible and durable usage on an introducer application.

9. ***Claims 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 37 above), and further in view of Trinder (US Patent 2,493,326).***

The modified Scarfone method discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Scarfone method, since the use thereof would provide an improved fluid flowing control method, in an introducer application.

10. ***Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Scarfone in view of West (as applied to claim 35 above), and further in view of Dressel (US Patent 5,102,410).***

The modified Scarfone method discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified Scarfone method, since the use thereof would provide an improved method to prevent fluid leak from an introducer.

11. ***Claims 17-22, 25, 26-29, 33, and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. (US Patent 5,755,693) in view of Scarfone et al. (US Patent 5,300,046), and further in view of West et al. (US Patent 6,322,541).***

Walker discloses an introducing apparatus and the method to use it, comprising: an elongate tubular sheath (18) having an external diameter, the sheath having a bore (24) including an internal diameter sized to receive a cannula (12; or the like)

therethrough, the sheath comprising a separable sheath (through 56, 58, and 18); the sheath extending from a distal end to a proximal end; the sheath including at least one tab (56, 58) extending away from a longitudinal axis of the sheath; and a movable valve assembly (64, 64a) movably coupled relative to the at least one tab, the moveable valve assembly adapted to move from a first position (See Fig. 12 and 15) to a second position (other than the first position, along 28), in the first position the movable valve assembly disposed through the longitudinal axis of the sheath, in the second position the movable valve assembly disposed away from the longitudinal axis of the sheath.

Walker discloses the invention, however, fails to disclose a side port assembly being coupled with the sheath.

The patent to Scarfone on the other hand, teaches that it is conventional in the sheath catheter assembly art, to utilize a side port assembly (See Figs. 1-2) attached to sheath catheter assembly (102), including a passage (126) permitting introduction of fluids through the side port assembly, and a stop cock assembly (128).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port assembly attached to the sheath as taught by Scarfone in the Walker device and method, since the use thereof would provide an improved sheath introducer, with additional fluid flowing through as needed.

The modified Walker device and method, however, fails to disclose the side port assembly being releasable coupled with the sheath.

The patent to West on the other hand, teaches that it is conventional in the art of a vascular introducer, to utilize a releasable snap-fit connection or thread-connection

coupling between a hub (22) and a cap (24)(see Col. 2, line 56 through Col. 3, line 8), with a sealing valve (26) inbetween them.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a releasable coupling of a snap-fit connection or thread-connection between the sheath and the side port assembly, as taught by West, in the modified Walker device and method, since the use thereof would provide an improved introducer and method of using it, with an attachable side port for a flush or injection of other fluid in a vascular access system.

12. ***Claims 23-24, 30-31, and 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone et al., and further in view of West et al. (as applied to claims 22, 26, and 35), and further in view of Trinder (US Patent 2,493,326).***

The modified Walker device and method discloses the invention, however, fails to disclose of opening the side port valve with a valve opening component associated with a side port coupling member.

The patent to Trinder on the other hand, teaches that it is conventional in the control of intractable nasal hemorrhages art, to utilize a valve opening component (See Figs. 4-5) to open a side port valve (10, S).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized a side port valve opening component as taught by Trinder in the modified Walker device and method, since the use thereof would provide an improved introducer and method, with a better control on the fluid flowing through.

13. ***Claims 32, 34, and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Walker et al. in view of Scarfone et al., and further in view of West et al. (as applied to claims 26 and 35), and further in view of Trinder (US Patent 2,493,326).***

The modified Walker device and method discloses the invention, however, fails to disclose of coupling a cap with the sheath after uncoupling the side port assembly.

The patent to Dressel on the other hand, teaches that it is conventional in the method a soft tissue cutting aspiration art, to couple a sheath with a cap (60) after uncoupling a side port assembly.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have coupled a sheath with a cap (60) after uncoupling a side port assembly, as taught by Dressel in the modified Walker device and method, since the use thereof would provide an improved method to prevent fluid leak from an introducer.

#### ***Response to Arguments***

14. Applicant's arguments with respect to claim 17-22 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ching Chang whose telephone number is (571)272-4857. The examiner can normally be reached on M-Th, 7:00 AM -5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Denion can be reached on (571)272-4859. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent Examiner



Ching Chang

  
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